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Description

ARTIFICIAL URINARY DIVERSION SYSTEM

The present invention relates to an artificial urinary diversion system according to the generic term of claim 1.

Among patients with urinary bladder disorder there is a plurality of findings, which require the removal of the own bladder. In this situation, a urinary diversion, by producing different sorts of reservoirs, is required. So-called wet diversions are distinguished, with direct urinary diversion via the ureters, which are implanted into the abdominal wall, or by insertion of a neutralized part of the intestine, in which the ureters are implanted and which is for its part implanted into the abdominal wall.

In both cases the urine is collected in a urine bag, which is stuck on the orifice.

Alternatively, the ureters are implanted into the rectum or - more and more in the past years - into replacement bladders, which are made of neutralized parts of the intestine.

These replacement bladders are either connected with the endogenous urethra or they are conducted out by creating an appropriate self-preserving occlusion mechanism at the abdominal skin, for example in the navel region.

Typical indicators for a replacement of the endogenous urinary bladder are advanced tumors at the urinary bladder, but there are also malformations, bladder impairments due to inflammation, as well as functional obstructions, such as for

example obstructions by urinating, or development of bladder atrophies among paraplegic people.

Thus, it is the object of the present invention to create an artificial urinary diversion system, which is adaptable to the different shapings of different persons and which shows the largest possible filling volume.

Further, it is an object of the present invention, that the artificial urinary diversion systems can be created such adaptable, without previous direct or indirect determination of the potentially available volume for said system that an as effective as possible determination and utilization during the surgical phase of the volume available in the patient is facilitated.

These objects are solved with the features of claim 1.

According to the application, the second area, which is arranged between the first and the third area, shows a cross-sectional surface that is smaller than the cross-sectional surface of the third area. By this it will be achieved, that a shape is provided, which can be adapted to almost any patient, and particularly, it is achieved that the largest possible filling volume can be provided, namely by simultaneous observance of the medical preconditions, such as for example the arteries and the intestine that pass after the operation laterally to the second area and on which no pressure must be put on. Attention must be paid to the fact that, with a person who is standing erect, the third area is arranged above the second and the first area. For example, if perhaps the first area shows a larger cross-sectional surface than the second area, it is also achieved that a so-called constriction will be provided in the second area, which is necessary for the bypassing arteries and/or the intestine and the kidneys, and

that a positional fixing with the first area is for example possible at the pubic bone (Symphysis Pubica).

Further advantageous embodiments of the following invention are subject matter of the sub-claims.

If, according to claim 2, the first, the second and the third area are modularly compounded or rendered modularly compoundable and if it has been paid attention to the fact that the respective transition surfaces between the individual areas are coordinated in a way, that a continuous transition is resulting, the advantage will be achieved that, according to the respective spatial condition of the patient, the individual areas of the urinary diversion system can be compounded and thus, it will be possible to take optimally account of the anatomical conditions of the patient.

If, according to claim 4, a fluid guidance is provided, which extends from the urinary bladder to the outlet in the first area, this corresponds to a large extent to the natural anatomy, which means, that among a person who is standing erect, the lowest, first area can be connected directly with the existing urethra, without using additional connection elements between the urethra and the outlet in the first area, which could possibly cause further medical complications.

If, according to claim 5, an actor or an actuator or a pump is provided in the third area, there is no need to provide an external pump, and, in view of the shaping, the first and the second area are not negatively influenced. Furthermore, with the advantageous embodiment that an actuator or a pump are provided in the third area, it is taken account to the fact that said third area, which is optimally embodied, is most likely to have the most space for the integration of a pump without extremely or negatively influencing the shaping.

If, according to claim 6, the pump is formed as a telescope device, the advantage that almost the total volume of the third area can be used for filling the contained urinary bladder can be achieved. Laboratory experiments have already shown that almost the total urinary bladder can be emptied with a telescope device, without leaving any sediment in the urinary bladder.

If, according to claim 7, the pump is formed as a lever pump, the advantage is achieved that no complex mechanics is integrated, such as for example for the use of a telescope device in the third area.

If, according to claim 8, the pump is formed as a screw pump, also the advantage, that almost the total volume of the third area can be used for the urinary bladder, is achieved. In addition, by using a screw pump, the advantage is given, that said screw pump pulverizes possible smaller urine crystals, so that these pulverized crystals can also be passed through a stenotic urethra.

If, according to claim 9, additionally a screw pump is arranged in a way, that it may possibly be displaced laterally to the fluid tube or duct, the advantage can be achieved, that an inlet and a lavage of the artificial urinary diversion system can be caused unproblematically, as the fluid tube will be opened by moving the screw. This practicability concerning the inlet and the lavage of the artificial urinary diversion system is for example very important in the field of spectroscopic examinations.

If, according to claim 10, a sphincter mechanism is preferably provided in the first area, the advantage is achieved, that almost a total control of the urinary

continency is possible. The ... can, for example, also be initi... sphincter mechanism

If, in addition, according to ... a control system is provided, which regulates the sp... anism, said control system, which is additionally ... further procedures, can for example also regulate ... and the closing of the sphincter.

If, according to claim 12, a sensor system is ... that controls the filling level of the urinary bladded ... a high degree of safety person concerned will be given a high degree of safety the person concerned using the artificial urinary bladders. This means that the person concerned does not have to void the urinary bladder regularly and in short intervals but said person can integrate in the everyday life in the usual way. If either a sound signal or a seismical signal, which will be produced at a certain filling level of the bladder, is sent to the concerned person, said person can move normally in the everyday life. However, it should be paid attention to the fact, that at least a security regulation is installed in the sensor system, which means, if a certain period of, for example 8 to 12 hours, is exceeded, it should be signaled to the person to void the bladder, independent from the filling level of said bladder. Furthermore, when controlling the filling level of the artificial bladder a security can be given, which is oriented at the physiological marginal conditions. By this it will be achieved that the artificial urinary diversion system operates similar to the function of the natural urinary bladder. This means, that with said urinary diversion system it will be achieved that, similar to the natural process, first the body signals the person that the urinary bladder should be emptied, then the bladder will be opened, the urine will be pressed out or squeezed and the bladder will be closed again.

If, according to claim 13, th… system will be controlled by the nerves responsible f… …inary bladder, an almost natural feeling will be giv… person with this neurological solution, …he concerned exogenous signal, such as for example prod… means, an signal or a seismical signal will thus not be nec… a sound …t.

If, according to claim 14, a power supply is ad… …nally provided in the urinary diversion system, a compact …ary diversion device can be provided, which can for example …st be integrated in the artificial urinary diversion syst… However, it is pointed out that the power supply can also be arranged separately, near the urinary diversion system in the patient, if, for reasons of space, a third area must be used, which does not allow an additional power supply.

If, according to claim 15, an external recharge device will make the power supply, the advantage is achieved, that the urinary diversion system can be almost lifelong provided with power. The charging of the counterpart of the external recharge device can be made by the adapted counterpart, which is charging wireless transcutaneously at an adapted main support place, which is implanted subcutaneously.

A simple power transfer can for example be achieved by the fact, that the recharge device cooperates inductively with the counterpart, with power being for example transferred inductively with frequencies tolerated by the body, for example 30 kHz.

If, according to claim 17, the power supply is made by primary batteries, which are integrated into the urinary diversion device, said urinary diversion device will work

without any continuing maintenance and the person concerned does not have to worry about the power supply.

It is also pointed out that, in case of need, for example the power for the actor system and/or the sensor system can be transferred wireless transcutaneously by placing a suitable transfer device onto the skin. However, it is hereby also necessary that the controlling and providing can also be executed by primary batteries as an additional power source. It is also possible that the total control and sensor system can be interrogated and started external telemetrically.

If, according to claim 18, additionally an actor system is integrated into the urinary diversion device, once again a completely independent system is provided, which only needs to be connected at the inlets or outlets with functional structures of the patient's urinary diversion system and which can be implanted as one compact part.

If, according to claim 19, the third area is constructed bipartite or in two-part form with, dependent on the filling level of the urinary bladder, one part being able to move away from the other part, it is for example possible to flexibly adjust the size of the urinary bladder and the filling level, in accordance with the requirements.

If, according to claim 20, the urinary diversion device shows two inlets in the third area, so that each ureter can be connected with the artificial urinary diversion system, it is thus not necessary to possibly provide a further separate additional element, for example in Y-shape, which can be used, if it is advantageous that the urinary diversion device does only have one inlet.

By providing one or more anti-reflux valves in the third area, in accordance with claim 21, it can be achieved that a reflux of the urine into the kidney is stopped. This also prevents a possible ascent of bacteria from the bladder up to the kidney.

If, according to claim 22, a fixing element is provided, it is easy to arrange and fix it in the human body.

If, according to claim 23, the fixing element is connected with the urinary diversion device via a dovetail joint, a tight or leak-proof connection has been constructed and the fixing element can be kept in the body, in order to be later connected at the right place with the urinary diversion device.

If, according to claim 24, the fixing element is moveably fixed via a guidance system, the urinary diversion device can, according to the anatomy of the person concerned, optimally be arranged and fixed. If furthermore the guide-rail system is integrated into the third area, there are no rails available that are protruding the third area, which could possibly influence the arranging in the human body or cause any functional or spatial inconvenience.

If, according to claim 25, the fixing element shows a splay or expanding element, which for example widens after implanting into the guide rails, a simple connection possibility is given, with especially guarantying a particular compatibility by the complete integration of the splay element into the fixing element.

If, according to claim 26, the fixing element is formed with biocompatible material, such as silicone, a well-tolerated material is given, but also the elasticity of the

silicone and others are taken into account due to the splay movements of the splay element.

Further preferred embodiments of the present invention are subject matter of the remaining sub claims.

Referring to the following drawings, said artificial urinary diversion system will be described in detail on the basis of a preferred embodiment.

Fig. 1 illustrates a schematic diagram of said artificial urinary diversion system;

Fig. 2 is a sectional drawing among the intersection line II -II;

Fig. 3 illustrates, in accordance with Fig. 1, a top view of said urinary diversion system;

Fig. 4 illustrates a bottom view of said urinary diversion system;

Fig. 5 is, in accordance with Fig. 1, said urinary diversion system with separated single areas;

Fig. 6 is a sectional view of the arranging of the urinary diversion system;

Fig. 7 is a front view of said urinary diversion system;

Fig. 8 is a top view of a body section regarding intersection VII - VII;

Fig. 9 illustrates a diagram, which shows the one executed polynomial function of 6^{th} degree regarding

the top surface outline of said urinary diversion system in accordance with Fig. 1;

Fig. 10 is a diagram, which shows the top-view silhouette of said urinary diversion system in accordance with Fig. 1, relating to the mentioned polynomial function of 6^{th} degree;

Fig. 11 is an embodiment of the fixing element;

The advantageous embodiment of said urinary diversion system explained in Fig. 1 includes a first area A, a second area B and a third area C, with the cross-sectional surfaces (illustrated hatched) that are perpendicular to the axial alignment of the urinary diversion device of the first, second and the third area, being so constructed, that the cross-sectional surface Q1 of the first area A is larger than the cross-sectional surface Q2 of the second area B and the cross-sectional surface Q3 of the third area C is in each case larger than the cross-sectional surface of the first and the second area. In addition, the first area A shows an outlet 3 and the third area C shows two inlets 5 for the urethras, which come from the respective kidneys.

The first area A of said urinary diversion system shows at its bottom surface 7 an increasing area D, with the shaping possibly being linear, arched, concave or convex, dependent on the patient's anatomic conditions for the urinary diversion system. In Fig. 1 it is clearly visible that the second area B, which is arranged between the first and the third area, is to be regarded as a constriction, with arteries being lead by laterally to its surfaces 9. The third area C, which comprises a urinary bladder, is shaped voluminously enough to allow a filling as large as possible. The two inlets for the renal urethra are provided at the front side of the third area.

Fig. 2 illustrates a laterally sectional view according to intersection II - II. With this sectional view it is clearly visible that the urinary diversion device 1 presented in Fig. 2 shows the top-side of a first outline K1. Here, in contrast to Fig. 1, the elevation of the second area B to the bottom surface 7 of the first area A is more clearly to see. In this embodiment, a curved or curvilinear elevation is shown. Said curved elevation serves to be brought into contact for example with the pubic bone and makes thus a positional fixing possible. It is also visible in Fig. 2 that below the third area so-called guide rails 13 are provided, in which a fixing element (not shown) can be inserted. At this point, special attention shall be drawn to the fact that a protruding of the guide rails may, for example, be avoided by complete integration into the third area.

Fig. 3 illustrates a top view of said urinary diversion system 1 and a second outline K2 in accordance with Fig. 1, with the constriction caused by the second area B being clearly visible, with the arteries being possible to be lead by laterally of the side surfaces 9. The relative proportions, which are shown between the first, the second and the third area, are also clearly visible.

Fig. 4 shows a bottom view of said urinary diversion system 1. The provided guide rails 13 for the fixing element are clearly indicated.

Fig. 5 illustrates said urinary diversion system 1, with its individual areas, i. e. first, second and third area, illustrated separately.

At this point it shall be noted that the division or sectioning into a first area, a second area and a third area

describes a preferred embodiment. Said urinary diversion system can also be provided with only two areas or as an integral entity. On the other hand, also more than three areas, which can be divided separately, are imaginable, with more areas of the increased adapting variation being taken into account.

Fig. 6 illustrates for example the arranging of said urinary diversion system. The first area A borders on the pubic bone, with the fixing element, which is moveably includable in the guide rails, being fixed for example at the respective places in the abdominal cavity.

Fig. 7 shows a front view for further illustration of the arranging of said urinary diversion system.

Fig. 8 is a top view, with the body section being above the section of said urinary diversion system.

Fig. 9 is for example a fit curve of the polynomial form $f(x) = a_6x^6 + a_5x^5 + a_4x^4 + a_3x^3 + a_2x^2 + a_1x + a$, i. e. a polynomial of 6th degree, which has been adapted to the first outline. The parameters used for this adapting are $a_6 = -9\cdot10^6$; $a_5 = 0{,}006$; $a_4 = -0{,}014$; $a_3 = 0{,}1638$; $a_2 = -0{,}9319$; $a_1 = 2{,}6778$ and $a = 0{,}8452$. However, it turned out that within a domain of $0 \leq X \leq 22$ the coefficients a_1 to a_6 in the domains $0<A<2$; $0<a_1<8$; $-2<a_2<0$; $0<a_3<1$; $-0{,}1<a_4<0$; $0<a_5<0{,}003$ and $-0{,}00001<a_6<0$ within a domain of $0<x<22$ can be taken.

Fig. 10 illustrates a top view of the half of a second outline, which has also been approximated with a polynomial of 6th degree. The parameters used for this were $a_6 = 1\cdot10^{-5}$; $a_5 = 0{,}008$; $a_4 = -0{,}0198$; $a_3 = 0{,}221$; $a_2 = -1{,}2703$; $a_1 = 3{,}9521$ and $A = 1{,}2557$. It has also turned out that these coefficients can

also be taken in the domains $0<A<2$; $0<a_1<8$; $-2<a_2<0$; $0<a_3<1$; $-0,1<a_4<0$; $0<a_5<0,003$; and $-0,00001<a_6<0$ within a domain of $0<x<22$, for adapting the respective second outline. To illustrate that Fig. 10 is a top view, the first outline and the fitted curve have been reflected at y = 0 at the x-axis of the diagram.

Fig. 11 illustrates a fixing element 15 with a front area F, which can be introduced into the guide rails of said urinary diversion system, and an end area E, which can, for example be pressed by hand.

Inside of said fixing element 15 there is a splay element (illustrated dashed), which is, due to the upright side surfaces 19A to 19D, for example taken along with the elastically formed fixing element 15 so that, for example, when impacting on the end area, the arms of the splay element 17 in the front area do also move towards each other and take the elastic material of the fixing element 15 with them.

Thus, the fixing element 15 can be narrowed in a way, that it can be included between the two guide rails 13. After introduction, the fixing element 15 will be released, so that, due to the elasticity of fixing element 15 the front area F will be re-given its original shape and a press fit/ tight fit may be achieved with the side surfaces of the guide rails. If now the fixing element 15 shall be moved within the guide rail 13, it is only necessary to re-press or re-contract the end area E, in order to open the press fit of the side surfaces of the front area F. The slots or openings 21 in the fixing element 13 serve for being tightly lead by the guide rails when the position of the fixing element might be re-aligned.

Thus, with this fixing element 15 said urinary diversion device can be arranged suitably before its final arranging and the fixing element can be fixed at the corresponding position in the abdominal cavity.

Due to this additional provision, which is providing a fixing element that is separately to the urinary diversion system, it is also possible to pre-fix the fixing element at places difficult to access for fixing a fixing element and to introduce it then into the urinary diversion device.

Instead of the screw pump, the pump using a telescope device and the lever pump all further sorts of pumps are imaginable for squeezing the urine, particularly a membrane pump or a gear pump.

The cross-sectional surfaces Q1, Q2 and Q3 can be different geometrical surfaces, such as quadratic, rectangular, trapezoidal, round, oval, elliptical or any other combination.